IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

United States of America,
Plaintiff,

v.

6,383 tablets, more or less, of an article of drug, labeled in part:

(bag) . .

"***Suplemento Natural SHANGAI *** Shangai Regular Estimulante sexual para Hombre y Mujer *** 100% Natural *** Marca Registrada *** 67390 *** Datos del Suplemento Tamano de la porcion: 1 Tableta ***"

43,162 capsules, more or lesss, of an article of drug, labeled in part:

(bag)

"*** Para Hombres Super SHANGAI *** Suplemento Natural 100% Natural *** SHANGAI *** Marca Registrada *** 67390 *** Datos del Suplemento Tamano de la porcion: 1 Tableta ***"

70,775 capsules, more or less, of an article of drug, labeled in part:

(bag)

"*** SHANGAI *** 100% Natural Ultra X *** Suplemento Natural SHANGAI *** Marca Registrada

Case No.: 08-1241 (SEC)

*** 67390 *** porcion: 1 Tableta ***"

301 capsules, more or less, of an article of drug, labeled in part:

(bag)

"*** Para Mujeres Lady SHANGAI *** Suplemento Natural 100% Natural *** SHANGAI *** Marca Registrada *** 67390 *** Datos del Suplemento Tamano de la porcion: 1 Tableta ***"

and

all other article of drug in any dosage form, regardless of the size or type of container, variously labeled or unlabeled, or that can otherwise be shown to contain or consist of any of the aforesaid products, including in-process products and an products awaiting repackaging or relabeling that are located anywhere on the premises of Shangai Distributor, Inc., Urb. Villa Madrid, 16 Street number M-14, Coamo, Puerto Rico,

Defendant.

VERIFIED COMPLAINT FOR FORFEITURE

TO THE HONORABLE COURT:

COMES NOW the United States of America represented by its undersigned attorneys and very respectfully allege and prays:

NATURE OF THE ACTION

1. This complaint and requests for seizure and condemnation of articles of drug described in the above caption, is filed by the United States of America in accordance with the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 301 et seq.

2. There are in Coamo, Puerto Rico, in the possession of Shangai Distributor, Inc., Urb. Villa Madrid, 16 Street number M-14, or elsewhere within the jurisdiction of this Court, articles of drug, as described in the above caption, which articles consist in whole or in part of components that were shipped in interstate commerce from outside the Commonwealth of Puerto Rico.

JURISDICTION AND VENUE

3. The United States brings this action in rem to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States, according to 28 U.S.C. 1345, and over seizures brought under the Act according to 21 U.S.C. 334.

4. This Court has in rem jurisdiction over the defendant property located in the District of Puerto Rico. Upon filing of this complaint, the plaintiff requests that the Court issue an arrest warrant in rem pursuant to Supplemental Rule G(3)(b), which the plaintiff will execute upon the property pursuant to Supplemental Rule G(3).

5. Venue is proper in this district pursuant to 28 U.S.C. 1395(b) and 21 U.S.C. 334(a)(1) because the defendant property is located at Shangai Distributor, Inc., Urb. Villa Madrid, 16 Street number M-14, Coamo, Puerto Rico.

BASIS FOR FORFEITURE

6. The articles described in the caption above are drugs, within the meaning of 21 U.S.C. 321(g)(1), that may not be introduced or delivered for introduction into interstate commerce, 21 U.S.C. 355(a), because they are "new drugs" according to 21 U.S.C. 321(p), and no approvals or applications for approval have been filed pursuant to 21 U.S.C. 355(b), or are in effect for such drugs.

7. The articles described in the caption above are misbranded while held for sale after shipment in interstate commerce, within the meaning of the Act, as follows:

a) because their labels fail to reveal that the articles contain the active pharmaceutical ingredients sildenafil, analogs of sildenafil, or tadalafil, which is a material fact with respect to adverse health consequences that may result from use of the articles by individuals with underlying medical conditions and at risk for adverse drug interactions or adverse drug side effects (21 U.S.C. 352[a], as further defined at 21 U.S.C. 321[n]); and

b) because their labeling fails to bear adequate directions for use, and they are not exempted from such requirement under 21 CFR 201.115, because the articles are unapproved new drugs(21 U.S.C. 352[f][1]).

8. For the reasons herein stated, the articles are held illegally within the jurisdiction of this Court and are liable for seizure and condemnation.

FACTS

9. Shangai Distributor, Inc., is engaged in the importation, repackaging, and distribution of various articles described in the caption of this case, which are labeled as natural supplements. However, these articles described in the aforementioned caption are promoted as drugs through claims made in their labeling, on the firm's website, on radio and television advertisements, and advertising painted in the firm's delivery van. Specifically, the articles are promoted as effective for the treatment of erectile dysfunction (Shangai Regular and Shangai Ultra), and impotence (Shangai Regular and Super Shangai). Lady Shangai is promoted as a sexual stimulant and to increase the strength of the kidneys and spleen. These articles are generally promoted as natural products without chemical additives.

10. In response to a consumer complaint, the Food and Drug Administration (FDA) conducted an inspection of Shangai

Distributors in November 2007. FDA laboratory analysis of a sample of Shangai Regular collected during the inspection revealed that it contained tadalafil, and a drug analog of sildenafil, a substance with a chemical structure very similar to and expected to have the same pharmacological activity as sildenafil. Tadalafil is the active pharmaceutical ingredient in Cialis and sildenafil is the active pharmaceutical ingredient in Viagra. Viagra and Cilais are both FDA approved prescription drugs for the treatment of erectile dysfunction (ED). FDA laboratory analyses of samples of Super Shangai, Shangai Ultra, and Lady Shangai collected during this inspection revealed the presence of sildenafil.

11. Although the articles to be seized purport to be dietary supplements, they can not be considered as such because they contain the active pharmaceutical ingredients sildenafil and tadalafil. Under the Act, 21 U.S.C. 321(ff)(3)(B), dietary supplements may not include articles approved as new drugs under 21 U.S.C. 355, unless the articles are marketed as a dietary supplement or food before its approval as a drug. FDA approved Viagra as a new drug on March 27, 1998, and sildenafil was not marketed as a dietary supplement or as a food before this date. FDA approved Cialis as a new drug on November 21, 2003, and tadalafil was not marketed as a dietary supplement or as a food before this date. Therefore, Shangai Regular, Super Shangai,

Shangai Ultra, and Lady Shangai are not dietary supplements.

12. Shangai Distributors was advised by FDA of the analytical findings of active pharmaceutical ingredients in their products and the potential adverse health risk posed by the products. They were also warned of the possible regulatory actions that may be taken if corrective and preventive actions are not implemented concerning the articles. The firm was largely unresponsive and did not commit to taking any corrective actions. Because of the health risk posed by the presence of undeclared pharmaceutical ingredients in the articles, FDA issued a News Alert on December 28, 2007, advising consumers not to buy or use the products. The Puerto Rico Department of Health Pharmacy Division also embargoed stock on hand at the firm on November 27, 2007.

WHEREFORE, the United States of America, respectfully requests from this Honorable Court to issue a Warrant of Arrest In Rem against the articles described in the caption of this case; that all persons having any interest in the articles be cited to appear herein and answer the allegations of the complaint; that this Court decree the condemnation of the articles and grant plaintiff the costs of this proceeding against the claimant of the articles; that the articles be disposed of as

this Court may direct pursuant to the provisions of the Act; and that plaintiff have such other and further relief as the case may require.

VERIFICATION

I, Carlos A. Medina, Compliance Officer, U.S. Food and Drug Administration, Department of Health and Human Services, have read the foregoing Complaint, and the statements contained therein are true to the best of my knowledge and belief. I declare under penalty of perjury that the foregoing is true and correct, this 27th. day of February, 2008.

Carlos A. Medina
Compliance Officer
U.S. Food and Drug Administration

RESPECTFULLY SUBMITTED, in San Juan, Puerto Rico, this 27th day February of 2008.

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